Ranvet’s Ulcerguard Oral Paste

Product Identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>Ranvet’s Ulcerguard Oral Paste</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms</td>
<td>Not Available</td>
</tr>
<tr>
<td>Other means of identification</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

Relevant identified uses of the substance or mixture and uses advised against

| Relevant identified uses | Ulcer treatment for horses. |

Details of the supplier of the safety data sheet

<table>
<thead>
<tr>
<th>Registered company name</th>
<th>Ranvet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>10-12 Green Street Banksmeadow NSW 2019 Australia</td>
</tr>
<tr>
<td>Telephone</td>
<td>+61 2 9666 1744</td>
</tr>
<tr>
<td>Fax</td>
<td>+61 2 9666 1755</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:info@ranvet.com.au">info@ranvet.com.au</a></td>
</tr>
</tbody>
</table>

Emergency telephone number

<table>
<thead>
<tr>
<th>Association / Organisation</th>
<th>Not Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency telephone numbers</td>
<td>+61 425 061 584</td>
</tr>
<tr>
<td>Other emergency telephone numbers</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

<table>
<thead>
<tr>
<th>Poisons Schedule</th>
<th>S4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
<td>Respiratory Sensitizer Category 1, Skin Sensitizer Category 1</td>
</tr>
</tbody>
</table>

Legend


Label elements

GHS label elements

SIGNAL WORD DANGER

Hazard statement(s)
Precautionary statement(s) Prevention

- **P261**: Avoid breathing mist/vapours/spray.
- **P280**: Wear protective gloves/protective clothing/eye protection/face protection.
- **P285**: In case of inadequate ventilation wear respiratory protection.
- **P272**: Contaminated work clothing should not be allowed out of the workplace.

Precautionary statement(s) Response

- **P304+P340**: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- **P342+P311**: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
- **P363**: Wash contaminated clothing before reuse.
- **P302+P352**: IF ON SKIN: Wash with plenty of soap and water.

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

- **P501**: Dispose of contents/container in accordance with local regulations.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

**Substances**

See section below for composition of Mixtures

**Mixtures**

<table>
<thead>
<tr>
<th>CAS No</th>
<th>%[weight]</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>66357-59-3</td>
<td>19</td>
<td>ranitidine hydrochloride</td>
</tr>
<tr>
<td>Not Available</td>
<td>&gt;60</td>
<td>performance additives nonhazardous</td>
</tr>
</tbody>
</table>

SECTION 4 FIRST AID MEASURES

**Description of first aid measures**

- **Eye Contact**: If this product comes in contact with eyes:
  - Wash out immediately with water.
  - If irritation continues, seek medical attention.
  - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

- **Skin Contact**: If skin contact occurs:
  - Immediately remove all contaminated clothing, including footwear.
  - Flush skin and hair with running water (and soap if available).
  - Seek medical attention in event of irritation.

- **Inhalation**: If fumes, aerosols or combustion products are inhaled remove from contaminated area.

- **Ingestion**: Other measures are usually unnecessary.

**Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

SECTION 5 FIREFIGHTING MEASURES

**Extinguishing media**

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

**Special hazards arising from the substrate or mixture**

- **Fire Incompatibility**: Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result...
Advice for firefighters

Fire Fighting
- Use water delivered as a fine spray to control fire and cool adjacent area.
- Do not approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.

Fire/Explosion Hazard
- The material is not readily combustible under normal conditions.
- However, it will break down under fire conditions and the organic component may burn.
- Not considered to be a significant fire risk.
- Heat may cause expansion or decomposition with violent rupture of containers.
- Decomposition may produce toxic fumes of: carbon dioxide (CO2), hydrogen chloride, phosgene, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.

HAZCHEM
- Not applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
See section 8

Environmental precautions
See section 12

Methods and material for containment and cleaning up

Minor Spills
- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Wear impervious gloves and safety glasses.
- Place spilled material in a clean, dry, sealable, labelled container.

Major Spills
- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Control personal contact with the substance, by using protective equipment.
- Prevent spillage from entering drains, sewers or water courses.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling
- Limit all unnecessary personal contact.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- When handling DO NOT eat, drink or smoke.

Other information
- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Keep cool. Store below 25 deg.C

Conditions for safe storage, including any incompatibilities

Suitable container
- Polyethylene or polypropylene container.
- Packing as recommended by manufacturer.
- Check all containers are clearly labelled and free from leaks.

Storage incompatibility
- Avoid reaction with oxidising agents

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)
INGREDIENT DATA
- Not Available

EMERGENCY LIMITS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Material name</th>
<th>TEEL-1</th>
<th>TEEL-2</th>
<th>TEEL-3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Continued...
### Exposure controls

**Appropriate engineering controls**

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:

- **Process controls** which involve changing the way a job activity or process is done to reduce the risk.
- **Enclosure and/or isolation of emission source** which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.

**Personal protection**

No special equipment for minor exposure i.e. when handling small quantities.

**Eye and face protection**

- Safety glasses with side shields.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.

**Skin protection**

See Hand protection below

**Hands/feet protection**

Wear general protective gloves, eg. light weight rubber gloves.

**Body protection**

See Other protection below

**Other protection**

- Overalls.
- Barrier cream.
- Eyewash unit.

**Thermal hazards**

Not Available

### SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

**Information on basic physical and chemical properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>Yellow brown viscous smooth paste, free of lumps; mixes with water.</td>
</tr>
<tr>
<td><strong>Physical state</strong></td>
<td>Free-flowing Paste</td>
</tr>
<tr>
<td><strong>Odour</strong></td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>Odour threshold</strong></td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>pH (as supplied)</strong></td>
<td>5-6</td>
</tr>
<tr>
<td><strong>Melting point / freezing point (°C)</strong></td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range (°C)</strong></td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>Flash point (°C)</strong></td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>Flammability</strong></td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Upper Explosive Limit (%)</strong></td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Lower Explosive Limit (%)</strong></td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Relative density (Water = 1)</strong></td>
<td>1.21-1.23</td>
</tr>
<tr>
<td><strong>Partition coefficient n-octanol / water</strong></td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature (°C)</strong></td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>Viscosity (cSt)</strong></td>
<td>8000-16000 @ 25C</td>
</tr>
<tr>
<td><strong>Molecular weight (g/mol)</strong></td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Taste</strong></td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>Explosive properties</strong></td>
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<tr>
<td><strong>Oxidising properties</strong></td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>Surface Tension (dyn/cm or mN/m)</strong></td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>Volatile Component (%vol)</strong></td>
<td>Not Available</td>
</tr>
</tbody>
</table>
### SECTION 10 STABILITY AND REACTIVITY

**Reactivity**
- See section 7

**Chemical stability**
- Product is considered stable and hazardous polymerisation will not occur.

**Possibility of hazardous reactions**
- See section 7

**Conditions to avoid**
- See section 7

**Incompatible materials**
- See section 7

**Hazardous decomposition products**
- See section 5

### SECTION 11 TOXICOLOGICAL INFORMATION

**Information on toxicological effects**

#### Inhaled
- Not normally a hazard due to non-volatile nature of product

#### Ingestion
- The material has **NOT** been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.

#### Skin Contact
- The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

#### Eye
- Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).

#### Chronic
- Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.

<table>
<thead>
<tr>
<th>Ranvet's Ulcerguard Oral Paste</th>
<th>TOXICITY</th>
<th>IRRITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Available</td>
<td>Not Available</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ranitidine hydrochloride</th>
<th>TOXICITY</th>
<th>IRRITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral (rat) LD50: 4190 mg/kg[^2]</td>
<td>Eye (rabbit): minimal OECD 405</td>
<td></td>
</tr>
<tr>
<td>IRE Assay: negative</td>
<td>Kay and Calandra score=3</td>
<td></td>
</tr>
<tr>
<td>Not likely to be a sever irritant</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Legend:**
1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.
2. Value obtained from manufacturer's SDS.

Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

---

**RANITIDINE HYDROCHLORIDE**

The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions.

Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins.

Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and eczema.

Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure.

Coma, pulse change, sweating, dyspnea, dermatitis after systemic, headache, hallucinations, convulsions, excitement, change in cardiac rate, somnolence, cyanosis recorded Respiratory or skin sensitization Respiratory sensitization May cause sensitization by inhalation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Occupational exposure Result: Positive Species: Human Skin sensitization May cause sensitization by skin contact. May cause an allergic skin...
reaction. Sensitization Occupational exposure- Result: Positive: Species: Human Optimisation Test: Result: Weak sensitiser: Species: Guinea pig Germ cell mutagenicity Based on available data, the classification criteria are not met. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Mutagenicity Ames Assay, GLP assay - Result: Negative Chromosomal Aberration Assay In Vivo, human lymphocytes, Ranitidine bismuth citrate tested: Result: Positive Chromosomal Aberration Assay In Vivo; germ cells, Maximum dose = 1000 mg/kg: Result: Negative - Species: Mouse GreenScreen Assay: Result: Negative Micronucleus Test: Result: Negative - Species: Rat Mouse Lymphoma Cell (LS178Y) Mutation Assay, GLP assay: Result: Negative SOS/umu Assay: Result: Negative Unscheduled DNA Synthesis in vivo, Maximum dose = 200 mg/kg: Result: Negative -Species: Rat; Organ: Stomach Yeast Mutation Assay: Result: Negative Carcinogenicity Based on available data, the classification criteria are not met. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Mutagenicity Ames Assay, GLP assay - Result: Negative Chromosomal Aberration Assay In Vivo, Ranitidine bismuth citrate tested: Result: Negative Chromosomal Aberration Assay In Vivo; germ cells, Maximum dose = 1000 mg/kg: Result: Negative -Species: Mouse Specific target organ toxicity - single exposure: Due to lack of data the classification is not possible. Specific target organ toxicity - repeated exposure Chronic effects Prolonged inhalation may be harmful

<table>
<thead>
<tr>
<th>Acute Toxicity</th>
<th>Carcinogenicity</th>
<th>Reproductivity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin Irritation/Corrosion</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious Eye Damage/Irritation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory or Skin sensitisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mutagenicity</td>
<td></td>
<td></td>
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<tr>
<td></td>
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Legend:
- Data available but does not fill the criteria for classification
- Data required to make classification available
- Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Endpoint</th>
<th>Test Duration (hr)</th>
<th>Species</th>
<th>Value</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Available</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

Legend:
Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

Persistence and degradability

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Persistence: Water/Soil</th>
<th>Persistence: Air</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No Data available for all ingredients</td>
<td>No Data available for all ingredients</td>
</tr>
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</table>

Bioaccumulative potential

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Bioaccumulation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No Data available for all ingredients</td>
</tr>
</tbody>
</table>

Mobility in soil

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Mobility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No Data available for all ingredients</td>
</tr>
</tbody>
</table>

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

- Recycle wherever possible or consult manufacturer for recycling options.
- Consult State Land Waste Management Authority for disposal.
- Bury residue in an authorised landfill.
- Recycle containers if possible, or dispose of in an authorised landfill.

Continued...
SECTION 14 TRANSPORT INFORMATION

Labels Required

<table>
<thead>
<tr>
<th>Marine Pollutant</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAZCHEM</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code
Not Applicable

SECTION 15 REGULATORY INFORMATION

Safety, health and environmental regulations / legislation specific for the substance or mixture

RANITIDINE HYDROCHLORIDE(66357-59-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS
Not Applicable

<table>
<thead>
<tr>
<th>National Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia - AICS</td>
<td>N (ranitidine hydrochloride)</td>
</tr>
<tr>
<td>Canada - DSL</td>
<td>N (ranitidine hydrochloride)</td>
</tr>
<tr>
<td>Canada - NDSL</td>
<td>N (ranitidine hydrochloride)</td>
</tr>
<tr>
<td>China - IECSC</td>
<td>N (ranitidine hydrochloride)</td>
</tr>
<tr>
<td>Europe - EINEC / ELINCS / NLP</td>
<td>Y</td>
</tr>
<tr>
<td>Japan - ENCS</td>
<td>N (ranitidine hydrochloride)</td>
</tr>
<tr>
<td>Korea - KECI</td>
<td>N (ranitidine hydrochloride)</td>
</tr>
<tr>
<td>New Zealand - NZIoC</td>
<td>Y</td>
</tr>
<tr>
<td>Philippines - PICCS</td>
<td>N (ranitidine hydrochloride)</td>
</tr>
<tr>
<td>USA - TSCA</td>
<td>N (ranitidine hydrochloride)</td>
</tr>
</tbody>
</table>

Legend:
Y = All ingredients are on the inventory
N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION

Other information
Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.
A list of reference resources used to assist the committee may be found at:
www.chemwatch.net

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations
PC-TWA: Permissible Concentration-Time Weighted Average
PC-STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit
IDLH: Immediately Dangerous to Life or Health Concentrations
OSF: Odour Safety Factor
NOAEL: No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index

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